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PUBLIC HEALTH SERVICE

COMMERCIAL EVALUATION LICENSE AGREEMENT

This **Agreement** is entered into between the National Institutes of Health (“**NIH**”) or the Food and Drug Administration (“**FDA**”), hereinafter singly or collectively referred to as “**PHS**”, agencies of the United States Public Health Service within the Department of Health and Human Services (“**HHS**”) through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and \_\_\_\_\_ (“**Licensee**”), a corporation of \_\_\_\_\_, having an office at \_\_\_\_\_.

1. Definitions:

- (a) “**Licensed Patent Rights**” means PCT or U.S. patent application(s) (including provisional patent application(s)) or patents and all foreign counterparts as follows: U.S. Patent Application Serial No. XX/XXX,XXX or U.S. Provisional Patent Application Serial No. XX/XXX,XXX, filed \_\_\_\_\_, entitled \_\_\_\_\_.
- (b) “**Materials**” means \_\_\_\_\_, including all progeny, subclones, or unmodified derivatives thereof.
- (c) “**Licensed Products**” means \_\_\_\_\_ and **Materials** made by **Licensee** within the scope of the **Licensed Patent Rights**.
- (d) “**Licensed Field of Use**” means \_\_\_\_\_.

- 2. **Licensee** desires to obtain a license to evaluate the commercial applications of the **Materials** and the **Licensed Products** and any inventions claimed in the **Licensed Patent Rights**.
- 3. **Licensee** intends to conduct laboratory experiments under this **Agreement** to evaluate the suitability for commercial development of inventions encompassed by the **Licensed Patent Rights**, **Materials** or **Licensed Products** in the **Licensed Field of Use**.
- 4. **Licensee** represents that it has the facilities, personnel, and expertise to evaluate the commercial applications of the **Materials** and the **Licensed Products** and the inventions encompassed by the **Licensed Patent Rights**, and that it shall expend reasonable efforts and resources on research and development of potential commercial products using the **Materials** or the **Licensed Products** and the inventions encompassed by the **Licensed Patent Rights**.
- 5. **PHS** hereby grants to **Licensee** a nonexclusive license for evaluation purposes only, within its research facilities, to make and use *but not to sell* the **Materials** or the **Licensed Products** and products and processes encompassed within the scope of a claim in the **Licensed Patent Rights**. **Licensee** agrees that any commercial or industrial use or sale of any such products or processes, including any formalized in-house screening programs, other than for evaluation purposes, shall be made only pursuant to the terms of a commercialization license to be negotiated in good faith by the parties. The rights provided herein are provided for the *evaluation of commercial applications only and not for commercial use*.

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6. **PHS** agrees, after receipt and verification of the license issue royalty, as required by Paragraph 9(a), to provide **Licensee** with samples of the **Materials**, as available, and to replace the **Materials**, as available, and at reasonable cost, in the event of their unintentional destruction. **PHS** shall provide the **Materials** to **Licensee** as specified in Appendix A.
7. **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of **PHS**.
8. This **Agreement** does not preclude **PHS** from distributing the **Materials** or **Licensed Products** to third parties for research or commercial purposes.
9. In consideration of the grant in Paragraph 5:
  - (a) **Licensee** hereby agrees to pay **PHS** a license issue royalty of \_\_\_\_\_ dollars (\$X) and payment is due within thirty (30) days of the effective date of this **Agreement**.
  - (b) This license issue royalty shall be paid in U.S. dollars and payment options are listed in Appendix B. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.
    - i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**; and
    - ii) Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.
10. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement**, unless the provisions of Paragraph 24 are not fulfilled, and shall expire \_\_\_\_\_ (X) months from its effective date. Upon termination or expiration of this **Agreement**, **Licensee** shall return all **Materials** and **Licensed Products** to **PHS** or provide **PHS** with written certification of their destruction, unless **Licensee** has executed a commercialization license for the **Licensed Patent Rights**.
11. In the event that **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice of the default, **PHS** may terminate this **Agreement** by written notice.
12. **Licensee** acknowledges that third parties also may be evaluating the **Licensed Patent Rights**, the **Licensed Products**, or the **Materials** for a variety of commercial purposes, and no guarantee can be made, should **Licensee** apply for a license, that such a license would be available for any particular field of use. **PHS** agrees to notify **Licensee** promptly if it receives from another company an exclusive license application in the **Licensed Field of Use** described in Paragraph 3.

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13. **Licensee** is encouraged to publish the results of its research projects using the **Licensed Products** or the **Materials**. In all oral presentations or written publications concerning the **Licensed Products** or the **Materials**, **Licensee** shall acknowledge the contribution by the named inventors to the **Licensed Products** or the **Materials**, unless requested otherwise by **PHS** or the named inventors.
14. **Licensee** agrees to submit in confidence a final report to **PHS** within thirty (30) days of termination or expiration of this **Agreement** outlining in general its results of commercial evaluation of the **Licensed Patent Rights**, the **Licensed Products**, or the **Materials** provided by this **Agreement**. **Licensee** shall submit the report to **PHS** at the Mailing Address for **Agreement** notices indicated on the Signature Page.
15. **PHS** agrees, to the extent permitted by law, to treat in confidence for a period of three (3) years from the date of disclosure, any of **Licensee's** written information about the **Licensed Patent Rights**, the **Licensed Products**, or the **Materials** that is stamped "CONFIDENTIAL" except for information that was previously known to **PHS**, that is or becomes publicly available, or that is disclosed to **PHS** by a third party without an obligation of confidentiality.
16. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE FITNESS FOR ANY PURPOSE OF THE **MATERIALS** OR THE **LICENSED PRODUCTS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **LICENSED PATENT RIGHTS** MAY BE EXPLOITED WITHOUT INFRINGING OTHER PATENT RIGHTS. **LICENSEE** accepts license rights to the **Licensed Patent Rights**, the **Licensed Products**, and the **Materials** "as is", and **PHS** does not offer any guarantee of any kind.
17. **Licensee** agrees to indemnify and hold harmless **PHS** and the Government of the United States of America from any claims, costs, damages, or losses that may arise from the practice of the **Licensed Patent Rights** or through the use of the **Licensed Products** or the **Materials**.
18. Neither party shall have any obligation to take any action with regard to an infringement of **Licensed Patent Rights** by a third party.
19. **Licensee** agrees in its use of any **Materials** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
20. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.
21. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Licensed Patent Rights**, the **Materials** and the **Licensed Products**.

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22. The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
23. Paragraphs 13, 15, 16, and 17 of this **Agreement** shall survive termination of this **Agreement**.
24. The terms and conditions of this **Agreement** shall, at **PHS**' sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

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## PHS COMMERCIAL EVALUATION LICENSE AGREEMENT

### SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

\_\_\_\_\_  
Steven M. Ferguson  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

\_\_\_\_\_  
Date

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch, DTD  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):  
by:

\_\_\_\_\_  
Signature of Authorized Official

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Title

I. Official and Mailing Address for **Agreement** notices:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

Mailing Address:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Email Address: \_\_\_\_\_

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

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## **APPENDIX A – SHIPPING INFORMATION**

**Licensee's Shipping Contact:** information or questions regarding shipping should be directed to Licensee's Shipping Contact at:

Shipping Contact's Name		Title
Phone: ()	Fax: ()	E-mail:

**Shipping Address: Name & Address to which Materials should be shipped (please be specific):**

Company Name & Department

Address:

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## **APPENDIX B – ROYALTY PAYMENT OPTIONS**

### **NIH/PHS License Agreements**

**\*In order to process payment via Electronic Funds Transfer sender MUST supply the following information:**

### **Procedure for Transfer of Electronic Funds to NIH for Royalty Payments**

Bank Name: Federal Reserve Bank

ABA# 021030004

TREAS NYC

BNF=/AC-75080031

OBI=Licensee Name and OTT Reference Number

Dollar Amount Wired=\$\$

NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

### **Mailing Address for Royalty Payments:**

National Institutes of Health

P.O. Box 360120

Pittsburgh, PA 15251-6120 USA

### **Overnight Mail for Royalty Payments only**

National Institutes of Health

360120

Mellon Client Service Center

Room 670

500 Ross Street

Pittsburgh, PA 15262-0001

(412) 234-4381 (Customer Service)

**Please make checks payable to: NIH/Patent Licensing**

**The OTT Reference Number *MUST* appear on checks, reports and correspondence**

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